IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:

10/811.277

Confirmation No.: 2164

Applicant

Shen-Ping Zhong et al.

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Examiner

Patterson, Marc A.

Title

THERMOPLASTIC MEDICAL DEVICE

Docket No.

1001.1728101

Customer No. :

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

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<u>June</u>, 2007.

By Joan Lindman

Dear Sir:

Appellant respectfully requests a Pre-Appeal Brief Review of the pending application. A Notice of Appeal is filed herewith.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413.

Appellants have carefully reviewed the Final Office Action of December 29, 2006 and the Advisory Action of April 2, 2007. Currently, claims 3, 5 and 7-52 are pending in the application and have been rejected. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claims 3, 5-17, 19-42 and 51-52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Rau et al. (U.S. Patent No. 6,024,722) in view of Huntjens (U.S. Patent No. 3,388,095). However, all elements of these claims are not disclosed in this combination of references. As such, these claims are allowable over these references.

For example, claim 31 recites "wherein the medical device comprises a second polymer, wherein the first polymer is not cross-linked and the second polymer is cross-linked." In the Final Office Action of December 29, the Examiner argues with regard to claim 31 that "Rau et al. disclose a blend of the first polymer and a second polymer."

Similarly, claim 51 recites "not cross-linking the first polymer while cross-linking the second polymer." This claim is rejected in the Final Office Action (again on page 5) by arguing that Rau et al. in column 1, line 43 "disclose a polymer which is crosslinked or is not crosslinked."

Neither of these rejections provides a rationale as to why Rau et al. discloses the elements as claimed. A cross-linked polymer has chemical bonds between otherwise separate polymer chains that a non cross-linked polymer does not have. There is therefore a structural difference between cross-linked and non cross-linked polymers. It does not follow from the Examiner's assertion that Rau et al. discloses a blend of polymers that Rau et al. discloses the claimed element of a medical device having a first polymer that is not cross-linked and a second polymer that is cross-linked.

Likewise, the alleged disclosure in Rau et al. of a polymer that may or may not be cross-linked does not show the claim element of not cross-linking a first polymer while cross-linking a second polymer as recited in claim 51. In fact, on page 6 of the Final Office Action, the Examiner makes a contradictory (but nevertheless incorrect) assertion with regard to claim 51, saying that "the first polymer disclosed by Rau et al. is a rigid rod polymer as discussed above, and is extruded as discussed above, and is therefore cooled from an extrusion process; Rau et al. therefore disclose a first polymer that is crosslinked." With regards to claims 51 and 52, therefore, the Examiner is making two mutually contradictory statements: that Rau et al. teaches that the first polymer is crosslinked and that Rau et al. teaches that the first polymer is not crosslinked. In fact, what Rau et al. teach as to the first polymer is irrelevant in this rejection, because the Examiner has indicated on page 3 that the first polymer is considered to be the

polyphenylene ether of Huntjens, which Rau et al. teaches nothing about. The Examiner has failed, therefore to demonstrate that the combination of Rau et al. and Huntjens teach or suggest each and every element of these claims and consequently the Examiner has not made a prima facie case of obviousness.

With regard to claim 5, which recites "wherein the first polymer comprises a plurality of benzoyl substituted 1,4 phenylene units," the Examiner argues in the Final Office Action, beginning on page 3, that "Rau et al. disclose a polymer comprising phenylene units" and therefore it would have been obvious to have selected benzoyl as the substituted unit "as bezoyl substituted 1,4 phenylene units are among the known phenylene units." This statement is purely conclusory and applicants have repeatedly traversed it.

Where the prior art discloses only a genus such as polymers containing a substantial number of polyvalent aromatic groups such as phenylene, the MPEP provides guidelines for determining the obviousness of a species (here benzoyl substituted 1,4 phenylene units) when the prior art teaches only the genus. MPEP 2144.08 states that "office personnel should [first] attempt to find additional prior art to show that the differences between the prior art primary reference and the claimed invention as a whole would have been obvious. Where such additional prior art is not found, Office personnel should follow these guidelines to determine whether a single reference 35 U.S.C. 103 rejection would be appropriate."

The steps the Examiner is instructed to take by the MPEP in such a case include determining whether one of skill in the art would have been motivated to selected the claimed species or subgenus by considering, among other factors, the size of the genus and the express teachings. Applicants understand phenylene to be a rather basic group which can be a constituent of many polymers, of which poly (1,4 phenylene) is only one. Similarly, benzoyl is but one functional group among many dozens of functional groups. There are consequently hundreds of subgenuses and species in the genus disclosed by Rau et al. Therefore, where there is no express teaching to use poly (1,4 phenylene) or to use benzoyl substituted poly (1,4 phenylene) in the cited reference or other teaching cited by the Examiner to use the claimed material over the many alternative polyphenlyne

polymers, there is no showing of obviousness. As such, the rejection of claim 5 over Rau et al. in view of Huntjens is improper and claim 5 is in condition for allowance.

With regard to claim 3, which recites "a medical device comprising an elongate flexible element made from a first polymer which is a substituted poly(1,4-phenylene)," the examiner argued that it would have been obvious to use the poly(2,6-dymethyl-1,4-phenylene) ether of Huntjens in the catheter of Rau et al. because Huntjens teaches "articles having unique physical properties over a broad temperature range (column 1, line 25" and therefore, "one of ordinary skill in the art would therefore have recognized the advantage of providing for the substituted 1,4 polyphenylene of Huntjens in Rau et al.." Final Office Action of December 29, 2006 at page 3.

However, one of ordinary skill would have recognized no advantages of using the polyphenylene ether of Huntjens in the catheter of Rau et al. A teaching that the polyphenylene ether has "a unique combination of...properties" (Huntjens at column 1, lines 24-26) is little more than puffery and would not have motivated one of skill in the art to make the suggested substitution. Moreover, if the polyphenylene ether of Huntjens has a unique combination of properties, it cannot have the same properties as those polymers already disclosed by Rau et al. as suitable for use with their catheter. Applicants can find no teaching in Huntjens which would suggest that the polyphenylene ether is more suitable than those polymers already disclosed by Rau et al. The teaching that polyphenylene ether can be used over a broad range of temperatures is of little interest to one making the catheter of Rau et al. This catheter is a balloon catheter used in body vessel lumens and, as such, applicants understand it to be exposed only to a relatively narrow range of temperatures centering about normal body temperature and this only for a limited period of time There is thus nothing that applicants can find in the teachings of Huntjens that would motivate one to substitute its polymer for that of Rau et al.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

SHEN-PING ZHONG F/T AL.

By their Attorney,

Date: 5 29 7007

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